8EHQ-0904-15753

September 27, 2004

Document Processing Center (7407M)
Attn: TSCA § 8(e) Coordinator
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: Submission of TSCA § 8(e) Health & Safety Study Cover Sheets:
Confidential and Public Versions

Dear TSCA 8(e) Coordinator:

Please find enclosed 81 TSCA Health & Safety Study Cover Sheets, pursuant to TSCA § 8(e). We are submitting a public display version and a confidential version, pursuant to EPA's confidentiality policy[1] and EPA's 2003 TSCA § 8(e) guidance.[2] The confidential version contains responses to EPA's Substantiation Questions for each of three categories of compounds.

Please do not hesitate to contact me at if you require any additional information or have questions regarding either the TSCA § 8(e) submissions or the responses to EPA's Substantiation Questions.

COMPANY SANITIZED

Enclosures

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1 TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance," 68 Fed. Reg. 33,129 at 33,140 (June 3, 2003).

2 "TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance," 68 Fed. Reg. 33,129 (June 3, 2003).

MR 279814

Tracking Number	Compound Type
04-147	Commercial Intermediate
04-148	Commercial Intermediate
04-163	Commercial Intermediate
04-176	Commercial Intermediate
04-183	Commercial Intermediate
04-193	Commercial Intermediate

TSCA HEALTH & SAFETY STUDY COVER SHEET - revised 9/15/04

TSCA CBI STATUS: **PUBLIC DISPLAY COPY**

CHECK IF THIS PAGE CONTAINS CONFIDENTIAL BUSINESS INFORMATION (CBI)

Clearly mark the confidential information with bracketing and check the box in the appropriate section (☐ *Contains CBI*). Submit a sanitized cover sheet with CBI deleted. Mark the sanitized copy, "Public Display Copy" in the heading.

1.0 SUBMISSION TYPE X Initial Submission

☐ 8(d) X 8(e) ☐ FYI ☐ 4 ☐ OTHER: Specify _____

2.1 SUMMARY/ABSTRACT ATTACHED (may be required for 8(e): optional for §4, 8(d) & FYI)	**2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID**	**2.3 FOR EPA USE ONLY**
X YES – See 6.0 below ☐ NO	04-147	

3.0 CHEMICAL/TEST SUBSTANCE IDENTITY X *Contains CBI*

Reported Chemical Name (IUPAC): *3-Chloro-2-methyl-propene*

CAS# - 563-47-3

Common Name: *Methallyl chloride*

4.0 REPORT/STUDY TITLE X *Contains CBI* *Study Number:*

Reproductive / Developmental Screening Toxicity

5.1 STUDY/TSCATS INDEXING TERMS [CHECK ONE]

HEALTH EFFECTS (HE): X ENVIRONMENTAL EFFECTS (EE): _____ ENVIRONMENTAL FATE (EF): _____

5.2 STUDY/TSCATS INDEXING TERMS (see instructions for 4 digit codes)

STUDY TYPE: RTOX SUBJECT ORGANISM (HE, EE only): RATS ROUTE OF EXPOSURE (HE only): GAVG VEHICLE OF EXPOSURE (HE only) Corn Oil

6.0 REPORT/STUDY INFORMATION X *Contains CBI*

Laboratory: Report/Study Date:

STUDY SUMMARY: Ten males and ten females were each dosed with 20, 60 and 180 mg/kg. There were no deaths or clinical and other signs observed, however, in the 180 mg/kg group, there was a decreased number of post implantation sites.

7.0 SUBMITTER INFORMATION X *Contains CBI*

Submitter: Title: Phone:

Company Name: Company Address:

Technical Contact: Phone:

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1.0 SUBMISSION TYPE X Initial Submission

☐ 8(d) X 8(e) ☐ FYI ☐ 4 ☐ OTHER: Specify _____

2.1 SUMMARY/ABSTRACT ATTACHED (may be required for 8(e): optional for §4, 8(d) & FYI)	2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID	2.3 FOR EPA USE ONLY
X YES – See 6.0 below ☐ NO	04-148	

3.0 CHEMICAL/TEST SUBSTANCE IDENTITY X *Contains CBI*

Reported Chemical Name (IUPAC): *3-Chloro-2-methyl-propene*

CAS# - 563-47-3

Common Name: *Methallyl chloride*

4.0 REPORT/STUDY TITLE X *Contains CBI* *Study Number:*

14-Day Oral Toxicity

5.1 STUDY/TSCATS INDEXING TERMS [CHECK ONE]

HEALTH EFFECTS (HE): X ENVIRONMENTAL EFFECTS (EE): _____ ENVIRONMENTAL FATE (EF): _____

5.2 STUDY/TSCATS INDEXING TERMS (see instructions for 4 digit codes)

STUDY TYPE: STOX SUBJECT ORGANISM (HE, EE only): RATS ROUTE OF EXPOSURE (HE only): GAVG VEHICLE OF EXPOSURE (HE only) Corn Oil

6.0 REPORT/STUDY INFORMATION X *Contains CBI*

Laboratory: Report/Study Date:

STUDY SUMMARY: Ten males and ten females were each dosed with 50, 150, 250 and 350 mg/kg. There were no deaths or clinical and other signs observed in the three lower dose groups. In the 350 mg/kg group, 3/10 males and 1/10 female rats died and there were signs of tremors.

7.0 SUBMITTER INFORMATION X *Contains CBI*

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1.0 SUBMISSION TYPE X Initial Submission

☐ 8(d) X 8(e) ☐ FYI ☐ 4 ☐ OTHER: Specify _____

2.1 SUMMARY/ABSTRACT ATTACHED (may be required for 8(e): optional for §4, 8(d) & FYI)	2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID	2.3 FOR EPA USE ONLY
X YES – See 6.0 below ☐ NO	04-163	

3.0 CHEMICAL/TEST SUBSTANCE IDENTITY ☐ *Contains CBI*

Reported Chemical Name (IUPAC): 2-Fluoro-5-nitroaniline

CAS# - 369-36-8

Common Name: *Substituted aniline intermediate*

4.0 REPORT/STUDY TITLE X *Contains CBI* *Study Number:*

Non-definitive Rat Oral

5.1 STUDY/TSCATS INDEXING TERMS [CHECK ONE]

HEALTH EFFECTS (HE): X ENVIRONMENTAL EFFECTS (EE): _____ ENVIRONMENTAL FATE (EF): _____

5.2 STUDY/TSCATS INDEXING TERMS (see instructions for 4 digit codes)

STUDY TYPE: ATOX SUBJECT ORGANISM (HE, EE only): RATS ROUTE OF EXPOSURE (HE only): GAVG VEHICLE OF EXPOSURE (HE only) CORN OIL

6.0 REPORT/STUDY INFORMATION X *Contains CBI*

Laboratory: Report/Study Date:

STUDY SUMMARY:

Rats were dosed at 50 mg/kg or 500 mg/kg. At 50 mg/kg, there were no mortalities (0/3 males and 0/3 females died) and no clinical symptoms. At 500 mg/kg there were no mortalities (0/3 males and 0/3 females died), however, there was decreased locomotion in 1 male rat at hour 3.

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1.0 SUBMISSION TYPE X Initial Submission

☐ 8(d) X 8(e) ☐ FYI ☐ 4 ☐ OTHER: Specify _____

2.1 SUMMARY/ABSTRACT ATTACHED (may be required for 8(e): optional for §4, 8(d) & FYI)	**2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID**	**2.3 FOR EPA USE ONLY**
X YES – See 6.0 below ☐ NO	04-176	

3.0 CHEMICAL/TEST SUBSTANCE IDENTITY ☐ *Contains CBI*

Reported Chemical Name (IUPAC): *2,2-Dimethyl-2,3-dihydro-benzofuran*

CAS# - 1563-38-8

Common Name: *7-hydroxybenzofuran*

4.0 REPORT/STUDY TITLE X *Contains CBI* *Study Number:*

Reproductive / Developmental Screening

5.1 STUDY/TSCATS INDEXING TERMS [CHECK ONE]

HEALTH EFFECTS (HE): X ENVIRONMENTAL EFFECTS (EE): _____ ENVIRONMENTAL FATE (EF): _____

5.2 STUDY/TSCATS INDEXING TERMS (see instructions for 4 digit codes)

STUDY TYPE: RTOX SUBJECT ORGANISM (HE, EE only): RATS ROUTE OF EXPOSURE (HE only): ORAL VEHICLE OF EXPOSURE (HE only) FOOD

6.0 REPORT/STUDY INFORMATION X *Contains CBI*

Laboratory: Report/Study Date:

STUDY SUMMARY: Groups of animals were treated prior to mating, during mating, through gestation and lactation until lactation day 4. The males were treated for a total of at least 28 days (pre-mating and post mating). Ten male and ten female rats were dosed at 10 ppm, 1,000 ppm and 5,000 ppm in the diet; there were no deaths or neurotoxic signs observed. Ten male and ten female rats were dosed at 10,000 ppm; there were no deaths, but signs of decreased body weights during gestation. Ten male and ten female rats were dosed at 20,000 ppm; there were no deaths, but there were signs of decreased litter size, corpora lutea and implantation sites.

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1.0 SUBMISSION TYPE X Initial Submission

☐ 8(d) X 8(e) ☐ FYI ☐ 4 ☐ OTHER: Specify _____

2.1 SUMMARY/ABSTRACT ATTACHED (may be required for 8(e): optional for §4, 8(d) & FYI)	**2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID**	**2.3 FOR EPA USE ONLY**
X YES – See 6.0 below ☐ NO	04-183	

3.0 CHEMICAL/TEST SUBSTANCE IDENTITY ☐ *Contains CBI*

Reported Chemical Name (IUPAC): *2,4-difluoroaniline*

CAS# - 5509-65-9

Common Name: *Dihaloaniline intermediate*

4.0 REPORT/STUDY TITLE X *Contains CBI* *Study Number:*

Non-Definitive Acute Oral Toxicity Study

5.1 STUDY/TSCATS INDEXING TERMS [CHECK ONE]

HEALTH EFFECTS (HE): X ENVIRONMENTAL EFFECTS (EE): _____ ENVIRONMENTAL FATE (EF): _____

5.2 STUDY/TSCATS INDEXING TERMS (see instructions for 4 digit codes)

STUDY TYPE: ATOX SUBJECT ORGANISM (HE, EE only): RATS ROUTE OF EXPOSURE (HE only): GAVG VEHICLE OF EXPOSURE (HE only) water

6.0 REPORT/STUDY INFORMATION X *Contains CBI*

Laboratory: Report/Study Date:

STUDY SUMMARY: Three males and three females were each dosed at both 50 and 500 mg/kg. None of the animals died. There were signs of neurotoxicity including tremors and staggered gait in 1/3 males and 1/3 females receiving 500 mg/kg.

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1.0 SUBMISSION TYPE X Initial Submission

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X YES – See 6.0 below ☐ NO	04-193	

3.0 CHEMICAL/TEST SUBSTANCE IDENTITY ☐ *Contains CBI*

Reported Chemical Name (IUPAC): *2,2-Dimethyl-2,3-dihydro-benzofuran*

CAS# -1563-38-8

Common Name: *7-hydroxy benzofuran*

4.0 REPORT/STUDY TITLE X *Contains CBI* *Study Number:*

Mouse micro-nucleus assay

5.1 STUDY/TSCATS INDEXING TERMS [CHECK ONE]

HEALTH EFFECTS (HE): X ENVIRONMENTAL EFFECTS (EE): _____ ENVIRONMENTAL FATE (EF): _____

5.2 STUDY/TSCATS INDEXING TERMS (see instructions for 4 digit codes)

STUDY TYPE: GTOX SUBJECT ORGANISM (HE, EE only): MICE ROUTE OF EXPOSURE (HE only): INTR VEHICLE OF EXPOSURE (HE only) CORN OIL

6.0 REPORT/STUDY INFORMATION X *Contains CBI*

Laboratory: Report/Study Date:

STUDY SUMMARY: In the toxicity assay, male and female mice were dosed with 200, 400, 600, or 800 mg/kg. Mortality was observed in 2/5 male and 5/5 female mice at 200 mg/kg, in 4/5 males and 2/5 females at 400 mg/kg and in 5/5 male and 5/5 female mice at 600 mg/kg and 800 mg/kg. Clinical signs following dose administration included: lethargy, piloerection, crusty eyes and hunched posture in males and females at 200 and 400 mg/kg. Convulsions were noted immediately after dose administration in males and females at 400, 600, and 800 mg/kg.

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